

## OSE Immunotherapeutics Reports Full Year 2022 Financial Results and Provides Business Strategy Update

### Financial highlights

- 2022 total turnover of €18 million driven by strategic partnerships with pharmaceutical companies.
- €25.6 million available cash as of December 31<sup>st</sup> 2022, including the drawdown of the second tranche of €10 million under a financing agreement with the European Investment Bank.
- Reinforced financial visibility until Q2 2024 supported by a recent bridge financing (detailed below: “Additive financing secured in 2023”).

### Clinical pipeline highlights

- Tedopi<sup>®</sup> (T-cell specific immunotherapy - cancer vaccine): Positive data on survival, safety and quality of life from Phase 3 trial in 3<sup>rd</sup> line in non-small cell lung cancer presented at ASCO & ESMO 2022; Confirmatory pivotal Phase 3 trial in preparation in 2<sup>nd</sup> line following FDA and EMA positive advice; Ongoing compassionate use in 3<sup>rd</sup> line in 3 European countries.
- OSE-127/S95011-lusvertikimab (IL-7R antagonist antibody): Phase 2 programs in Sjögren syndrome and ulcerative colitis with main results expected in 2023.
- OSE-172/BI765063 (SIRPα antagonist antibody): Phase 1 clinical expansion trial initiated in advanced hepatocellular carcinoma and head and neck cancer.
- FR104/VEL-101 (CD28 antagonist antibody): Clinical Phase 1 completed by Veloxis in the US and ongoing Phase 1/2 in kidney transplantation.
- OSE-279 (PD1 antagonist antibody): First patient dosed in Phase 1/2 clinical trial in solid tumors and lymphomas.

Nantes, France – April 27, 2023, 6:00 p.m. CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) today reported its consolidated annual financial results for 2022 and provided an update on key clinical and preclinical achievements, on ongoing collaboration and licensing agreements, as well as on the 2023 Company’s outlook.

### **Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics, comments:**

*“We have achieved significant milestones in 2022, advancing our assets both in the clinical and preclinical stage, while strengthening our financial position despite a difficult economic environment. First, I would like to thank our team, our scientific, clinical, pharmaceutical experts and our pharma*

*partners for their continuous commitment. I would also like to thank our institutional partners, the Region Pays de la Loire, our banks and Bpifrance for their contribution for securing a bridge financing to support our strategic leading immunotherapy programs.*

*We have recently seen renewed interest for cancer vaccines in the field of Immuno-Oncology and the Phase 3 results of Tedopi® post IO failure contributed significantly to this new momentum. Well protected by recent granted patents families and orphan status in the US for the HLA-A2 population, Tedopi® is the most advanced cancer vaccine candidate worldwide in the domain of acquired resistance to immune checkpoint. We are also dedicated to the development of the most-advanced anti-IL-7R product within the framework of a license option agreement with Servier. Our other international pharma partners Boehringer Ingelheim and Veloxis are actively engaged in the development of respectively OSE-172/BI 765063 in hepatocellular carcinoma and head and neck cancers and FR104/VEL-101 in kidney transplant.*

*Today, the Company has solid clinical and preclinical innovative assets and, like many European biotech companies, is striving to create more sustainable and higher value. My ambition for OSE is twofold: on the one hand, to generate near-term value by bringing our proprietary clinical assets until marketing registration with commercialization through regional established partners. This strategy is based on prioritizing investments when a selected niche indication is clearly identified based on a strong biological rationale and with acceleration opportunities in the development. On the other hand, to generate long-term recurrent revenue through collaborations and licensing agreements with global pharma partners for our programs targeting large indications and requiring larger investments.*

*We look forward reaching new key milestones in 2023 with significant potential inflection points, including clinical readouts and further updates on our preclinical programs. I am confident that we shall find the next strategic pharma partners and have all the relevant internal capabilities to support them in bringing our pre-IND assets to the next stage and demonstrating clinical proof of efficacy. OSE-230 (anti-ChemR23 agonist mAb) is one of our key preclinical assets with initiated IND-enabling studies to be ready for clinical Phase 1 in 2024 in the new attractive field of chronic inflammation resolution.*

*The progress we have made these last years has positioned OSE to deliver multiple major milestones in the next 12 months, including launching a registrational Phase 3 trial for the most advanced therapeutic vaccine candidate. I strongly believe that OSE has a very exciting future and is well positioned to meet all of its key stakeholders' expectations. OSE is at the forefront to transform breakthrough scientific and technological discoveries into therapeutic innovations for the benefit of patients."*

**Anne-Laure Autret-Cornet, Chief Financial Officer of OSE Immunotherapeutics, adds:** *"Recurrent turnover is driven by collaborations and licensing agreements with pharma companies. We have secured financial visibility for over the next 12 months, supported, in parallel, by a strict review of strategic expenses and their prioritization, to manage our cash level. This new flexible and scalable funding operating model, in addition to other available sources of financing, allows us to pursue our investments to increase the value and interest of our assets."*

## CLINICAL PROGRESS IN IMMUNO-ONCOLOGY AND IMMUNO-INFLAMMATION

### IN IMMUNO-ONCOLOGY

#### **TEDOPi®, an immunotherapy activating tumor specific T-cells**

***Major regulatory progress on the clinical development plan; A further confirmatory Phase 3 trial to support the registration of Tedopi® as a potential new standard of care in second line for non-small cell lung cancer (NSCLC) patients in secondary resistance to immune checkpoint inhibitors (ICI); Authorizations for compassionate use in NSCLC in third line in France, Italy and Spain.***

- The US Food and Drug Administration (FDA) and the European Medicines Agencies (EMA) supported the continuation of the clinical development for Tedopi® through a new confirmatory phase 3 clinical trial versus standard of care in second line treatment for HLA-A2+ patients in advanced non-small cell lung cancer (NSCLC) with secondary resistance post-ICI (Immune Checkpoint Inhibitors) failure\*. OSE Immunotherapeutics is progressing on the protocol development for this next confirmatory Phase 3 pivotal trial to support the regulatory registration in second line treatment. The protocol design is developed with the support of the international NSCLC clinician experts' group which were already involved in the previous phase 3 ATALANTE trial.
- The significant medical need for new therapeutic options in NSCLC patients post-ICI failure associated with promising efficacy, safety and quality of life data from the initial Phase 3 trial of Tedopi® (ATALANTE-1) resulted in authorizations for compassionate use\*\* of Tedopi® delivered by Health Agencies in Europe - in September 2022 in France and in Italy and in March 2023 in Spain through a Special Situation Authorization\*\*\* - in third line post-chemotherapy and immunotherapy.

\* Secondary resistance: after at least 12 weeks of ICI treatment in monotherapy (Task force SITC 2020 - Kluger H et al 2020).

\*\* Compassionate use is a treatment option that allows for the use of an unauthorized medicine. Under strict conditions, products in development can be made available to nominative patients who have a disease with no satisfactory authorized therapies and who cannot enter clinical trials (<https://www.ema.europa.eu/en/human-regulatory/research-development/compassionate-use>).

\*\*\* The Special Situation Authorization ([Real Decreto 1015/2009](#)) is intended to provide early access to medicines for patients with a severe or rare disease with high unmet need and for which no authorized therapeutic alternatives are available.

***Positive clinical results presented at the American Society of Clinical Oncology (ASCO) and at the European Society for Medical Oncology (ESMO) 2022 annual meetings.***

- Final data of Phase 3 Atalante-1 in NSCLC patients after failure to ICI were presented at ASCO 2022 with significantly better Patient Reported Outcomes (PROs) in the Tedopi® arm versus chemotherapy in the primary analysis for the population of interest (n=118 patients) and confirmed in the global population (n=219 patients).
- The results presented at ESMO 2022 have shown that in advanced HLA-A2+ NSCLC patients with IO secondary resistance after sequential CT-IO (n=118), overall survival was longer with Tedopi® versus SoC regardless of the use (or not) of post progression anticancer treatment (with 13.5 months versus 10.6, HR=0.71; without 6.3 months versus 4.5, HR=0.76).
- A second analysis presented at ESMO 2022 assessed the Net Treatment Benefit (NTB), a new statistical method combining efficacy, safety and quality of life, of Tedopi® versus SoC in patients with NSCLC who failed therapy with immune checkpoint inhibitors. NTB of Tedopi® in the overall population (n=219) was of 19% and reached statistical significance (p=0.035).
- The first interim results from the Phase 2 clinical trial TEDOPaM evaluating Tedopi® in advanced or metastatic pancreatic ductal adenocarcinoma, in monotherapy or in combination with nivolumab or

FOLFIRI after induction with FOLFIRINOX were presented at ASCO 2022. The primary endpoint of the trial is the one-year survival rate (Fleming- futility analysis; null hypothesis <25%), and the key secondary endpoint was the Time to maintenance Strategy Failure (TSF= maintenance time + FOLFIRI reintroduction). The GERCOR oncology clinician group and the PRODIGE Intergroup are sponsors of this study.

**BI 765063/OSE-172, a myeloid checkpoint inhibitor developed in partnership with Boehringer Ingelheim**

- In May 2022, the initiation of the Phase 1 clinical expansion trial with BI 765063 sponsored and conducted by Boehringer Ingelheim triggered a €10 million milestone payment from Boehringer Ingelheim to OSE Immunotherapeutics. The trial is conducted in advanced hepatocellular carcinoma and head and neck cancer patients in combination, in particular with anti-PD-1 antibody ezabemlimab.

**OSE-279, anti-PD1 monoclonal antibody: first patient dosed in the Phase 1/2 clinical trial in patients with advanced solid tumors or lymphomas**

- In December 2022, the first patient was dosed in this first-in-human open label Phase 1/2 dose escalation and expansion study. The trial aims to determine the Maximum Tolerated Dose and/or the recommended Phase 2 dose of OSE-279 in monotherapy in advanced solid tumors or lymphomas. Secondary objectives include assessment of OSE-279's antitumor activity, evaluation of the safety profile, pharmacokinetic and receptor occupancy or pharmacodynamic profile.

**IN IMMUNO-INFLAMMATION**

**OSE-127/S95011-lusvertikimab, a monoclonal antibody antagonist of the interleukin-7 receptor**

The main results are expected for H1 2023 for the phase 2 in Sjögren syndrome (Servier sponsorship) and Q4 2023 for the phase 2 in ulcerative colitis (OSE Immunotherapeutics sponsorship). Servier has the right to exercise the second option provided in the license agreement based on the Phase 2 clinical studies.

- Positive preclinical efficacy data in B- and T-Cell Acute Lymphoblastic Leukemia (B- and T-ALL): the latest preclinical data on the use of OSE-127 for the treatment of B- and T-Cell ALL (B- and T-ALL) were presented at the American Society of Hematology (ASH) annual meeting in December 2022. This oral presentation has received the merit-based "Abstract Achievement Award" from the peer-review committee. The presentation, entitled "[The IL7R-Antagonist OSE-127 Blocks Acute Lymphoblastic Leukemia Development Via a Dual Mode of Action](#)", reported on the preclinical efficacy of OSE-127 in ALL and on the dual mechanism of action underlying its anti-leukemic efficacy.

**VEL-101/FR104, a monoclonal antibody antagonist of CD28 developed in partnership with Veloxis Pharmaceuticals, Inc. in transplantation**

- In January 2022, Veloxis obtained acceptance of the IND from the Food & Drug Administration (FDA) for a clinical trial with VEL-101/FR104 sponsored and conducted by Veloxis in the US. Based on the global license agreement signed in April 2021, this first milestone triggered a €5 million payment from Veloxis to OSE Immunotherapeutics.
- In February 2022, Veloxis obtained Fast Track Designation from the FDA for VEL-101/FR104 which is developed for prophylaxis of renal allograft rejection in recipients of kidney transplants.
- In May 2022, the first patient was dosed in the Phase 1 conducted by Veloxis Pharmaceuticals, Inc. This study was completed in 2023.

## PRECLINICAL PROGRESS IN IMMUNO-ONCOLOGY AND IMMUNO-INFLAMMATION

### - MYELOID PLATFORM

#### **OSE-230, first monoclonal antibody to activate a pro-resolutive GPCR target (ChemR23) in the resolution of inflammation**

- Presentation at the Protein & Antibody Engineering Summit (PEGS) 2022 annual meeting reporting on ChemR23's over-expression is associated with chronic neutrophil accumulation in damaged tissues. OSE-230 is the first monoclonal antibody to activate a pro-resolutive GPCR target (ChemR23). Its innovative mechanism of action drives inflammatory neutrophil tissue clearance through apoptosis and inhibition of the pathogenic NETosis\*\*\*\* process. This mAb triggered resolution demonstrated positive preclinical efficacy in chronic colitis or chronic arthritis models with significant decrease in tissue fibrosis and restoration of tissue healing.

#### **CLEC-1\*\*\*\*\* (a C type lectin receptor), a novel myeloid immune checkpoint beyond the SIRPα/CD47 axis**

- Presentations at the Immuno-Oncology Summit Europe in May 2022, Tumor Myeloid-Directed Therapies Summit in June 2022 and Society for Immunotherapy of Cancer (SITC) meeting in November 2022 reported on:
  - The identification and validation of CLEC-1 as novel immune checkpoint target and development of its antagonists as an innovation in cancer immunotherapy to enhance myeloid cell functions and promote tumor antigen presentation to bridge the innate and adaptive immune system.
  - CLEC-1 has the ability to sense dead or stress tumor cells through the identification of a CLEC-1 protein ligand (CLEC-1 ligand) over-expressed in cancer cells. Mechanistically, CLEC-1's expression by dendritic cells controls the cross-presentation of dead-cell tumor associated antigens and hence CD8+ T-cell cross-priming. Reversely, the absence of CLEC-1 increases the phagocytosis of tumor cells by macrophages *in vivo*. Proprietary anti-CLEC-1 mAbs increase survival in monotherapy in orthotopic model of hepatocellular carcinoma while combination with chemotherapy increases preclinical tumor eradication in colon carcinoma model.
- In November 2022, an article entitled "*CLEC-1 is a death sensor that limits antigen cross-presentation by dendritic cells and represents a target for cancer immunotherapy*" was published in the peer-reviewed journal Science Advances.
  - The article reported on fundamental discoveries and preclinical results showing that CLEC-1 is a novel myeloid checkpoint interacting with a new ligand TRIM-21 and highlighting the CLEC-1/TRIM21 axis as a new target for cancer immunotherapy.

\*\*\*\* NETosis is a program for formation of neutrophil extracellular traps (NETs), which consists of modified chromatin decorated with bactericidal proteins from granules and cytoplasm. Recent research has highlighted those neutrophils, and in particular NETs that can be released upon activation, have central roles in the initiation and perpetuation of systemic autoimmune disorders and trigger complex and chronic inflammatory responses that lead to organ damage and fibrosis.

\*\*\*\*\*Collaborative program between OSE Immunotherapeutics and Dr Elise Chiffolleau's (<https://cr2ti.univ-nantes.fr/research/team-1>) research teams (Center for Research in Transplantation and Translational Immunology (CR2TI), UMR1064, INSERM, Nantes University at Nantes University Hospital).

- **BiCKI® PLATFORM**

**BiCKI®IL-7v, a novel bispecific therapy combining anti-PD-1 and the cytokine IL-7**

- Presentations at the American Association for Cancer Research (AACR) in April 2022 and Society for Immunotherapy of Cancer (SITC) meeting in November 2022 reported on:
  - The presentation highlighted the differentiation of the novel bispecific therapy combining anti-PD1 and IL-7 cytokine and positioned it as a high potential asset for cancer patients suffering from immune escape following checkpoint inhibitor treatments.
  - High IL-7 receptor (IL-7R) pathway expression in TILs (Tumor-Infiltrating Lymphocytes) and tumor-specific T-cell clonotypes is predictive of long-term immune checkpoint inhibitor clinical responses. Reversely, decreased IL-7R pathway expression is associated with metabolic stress and apoptosis of tumor-specific T-cells. Redirecting IL-7 selectively on PD1 expressing T-cells provides stemness, proliferative and survival signals to tumor-specific T-cells inducing durable anti-tumor responses.

**A STRONG GLOBAL INTELLECTUAL PROPERTY STRATEGY**

37 new patents granted:

- **Tedopi®**
  - Five new patents (Europe, United States, Japan, China – including Hong-Kong and Macao – and Mexico) related to a new emulsion manufacturing process validated for the ready-to-use peptides combination (process and product protected), until 2038.
  - A Japanese patent for the use of Tedopi® after failure with PD-1 or PD-(L)1 immune checkpoint inhibitor treatment in HLA-A2 positive cancer patients, until 2037.
  - A Eurasian patent covering the regimen of administration (inducing early T memory response) of Tedopi®, until 2035.
- **OSE-127**
  - Seven patents (United States, Eurasia, New Zealand, Ukraine, Malaysia, Costa-Rica and Salvador) covering anti-CD127 antibodies (notably OSE-127), until 2035.
  - Ten patents (Australia, Eurasia, Mexico, Malaysia, New-Zealand, Russia, Ukraine, Taiwan, Chili and Pakistan) covering humanized anti-CD127 antibodies, until 2037.
- **OSE-172:** Four patents (United States, Japan, Korea and ARIPO (Africa)) covering anti-SIRPα antibodies, until 2036-2037.
- **OSE-279:** Six patents (United States, Japan, Korea, China, Mexico and Colombia) for OSE-279 and its use in cancer treatment, until 2039.
- **CLEC-1:** Three patents (United States, Japan and Israel) covering CLEC-1, novel myeloid immune checkpoint target for cancer immunotherapy, until 2037.

**CORPORATE GOVERNANCE - NEW CHIEF EXECUTIVE OFFICER (CEO), NEW BOARD OF DIRECTORS MEMBER AND NEW INTERNATIONAL SCIENTIFIC ADVISORY BOARD (SAB)**

**Appointment of Nicolas Poirier as CEO**

Nicolas Poirier was appointed Chief Executive Officer of OSE Immunotherapeutics on October 7, 2022.

Throughout his career, Nicolas Poirier has demonstrated both his expertise as an international scientific leader, pioneering the discovery and development of innovative immunotherapies, and in-depth knowledge of the biotech sector through various strategic leadership roles. He has been instrumental in the development of OSE

Immunotherapeutics, notably as the initiator of 5 programs in the Company's portfolio that are now in clinic. He also played a major role in the signature of 4 strategic pharmaceutical partnerships for OSE Immunotherapeutics.

**Appointment of Alexandre Lebeaut as an Independent Member of the Board of Directors**

Alexandre Lebeaut was appointed independent Director of OSE Immunotherapeutics on February 18, 2022.

Alexandre Lebeaut has more than 25 years of a valuable experience and leadership both in innovation, research and development, from preclinical to post-marketing stage and with major achievements in particular in immunology, oncology, immuno-inflammation and infectious diseases. He has held various global positions, notably in the United States at Bluebird Bio, Sanofi, Novartis and Schering Plough Research Institute. Most recently, Alexandre Lebeaut served as Executive Vice-President R&D and Chief Scientific Officer at Ipsen in the US.

**A newly formed SAB combining the expertise of renowned scientific and international key-opinion leaders in the fields of immunology, immuno-oncology, inflammation and immunotherapy**

- The SAB, appointed in June 2022, works with the Company’s leadership team and advises its Board of Directors on its scientific and medical strategy.
- The SAB includes Pr. Wolf-Hervé Fridman (Université de Paris), Dr. Sophie Brouard (CRTI, Nantes), Dr. Bernard Malissen (CIML, Marseille), Pr. Miriam Merad (Mount Sinai, New-York), Pr. Charles Serhan (Harvard, Boston) and Dr. Jennifer Wargo (MD Anderson Cancer Center, Houston).

**2022 FINANCIAL RESULTS**

A meeting of the Board of Directors of OSE Immunotherapeutics was held on April 27, 2023. Following the Audit Committee opinion, the Board approved the annual and consolidated financial statements prepared under IFRS on 31 December 2022.

The key figures of the 2022 consolidated annual results are reported below (and presented in the attached tables):

In K€	December 31, 2022	December 31, 2021
Current operating result	(18,392)	(16,625)
Operating result	(18,476)	(16,625)
Net result	(17,760)	(16,850)
Available cash*	25,620	33,579
Consolidated balance sheet	91,781	101,876

As of December 31, 2022, the Company’s available cash totaled €25.6 million, versus €33.6 million as of December 31, 2021.

In 2022, OSE Immunotherapeutics received:

- €10 million milestone payment as part of the global collaboration and license agreement with Boehringer Ingelheim for BI 765063, a SIRPα inhibitor on the SIRPα/ CD47 myeloid pathway.
- €5 million milestone payment as part of the license agreement with Veloxis Pharmaceuticals Inc. for VEL-101/FR104, anti-CD28, in transplant indications.

- €10 million payment corresponding to the second tranche of a €25 million loan agreement by the European Investment Bank.

#### **ADDITIVE FINANCING SECURED IN 2023:**

The global economic crisis and political uncertainty driven by the war in Russia-Ukraine have triggered a global major instability in the financial markets and high inflation that have strongly impacted the life sciences and biopharmaceutical industry since 2022. In this adverse context, OSE Immunotherapeutics has secured additional funding options to strengthen its financial visibility beyond 12 months.

#### **Equity financing line**

To supplement its financial resources and in order to extend its financial visibility until the second quarter of 2024, OSE Immunotherapeutics has signed on 27 April 2023, an equity financing line with Vester Finance<sup>1</sup>.

In accordance with the terms of the agreement, Vester Finance has undertaken to subscribe to a maximum of 2,800,000 shares of the Company, representing a maximum of 14.8% of the share capital, on its own initiative, over a maximum period of 24 months, subject to certain usual contractual conditions.

The shares will be issued on the basis of an average stock market price preceding each issue<sup>2</sup>, reduced by a maximum discount of 6%, in compliance with the price rule and the ceiling set by the general assembly meeting<sup>3</sup>.

OSE Immunotherapeutics is committed to a minimum use of the line of financing in the amount of 0.6 million euros, beyond which the Company retains the option of suspending or terminating this agreement at any time and without costs or penalties.

This transaction was decided by the Company's Board of Directors of the Company acting on delegation from the general assembly meeting of shareholders of June 23, 2022<sup>4</sup>.

Assuming that this line of financing is used in full, a shareholder holding 1.00% of the capital of OSE Immunotherapeutics before its establishment, would see his stake increase to 0.87% of the capital on an undiluted basis<sup>5</sup> and 0.88% of the share capital on a diluted basis<sup>6</sup>.

This transaction does not give rise to the preparation of a prospectus subject to the approval of the "Autorité des Marchés Financiers", on the basis of Article 1 of the Prospectus Regulation granting an exemption when a transaction relates to a dilution less than 20% of the Company's share capital.

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<sup>1</sup> This equity financing line was advised, structured and subscribed by Vester Finance, which usually invests in growth companies known as "small caps", particularly in the life science and biotechnology sectors. Vester Finance may, as an investor, resell the shares in the more or less short term. Vester Finance and its manager benefit from a 20 year- experience, have conducted more than 100 similar operations, one of which has obtained the « Prize for the best financing operations of the year » from the "Club des Trente". Over the last 25 equity financing line transactions carried out by Vester Finance, the company's stock exchange prices have increased by an average of +18% and market capitalizations by +52% (source: Vester Finance).

<sup>2</sup> Lower daily average volume-weighted stock market price over the period of the two trading sessions preceding each issue.

<sup>3</sup> The issue price of the shares must be "at least equal to the weighted average of the prices of the last three trading sessions preceding the setting of the issue price, possibly reduced by a maximum discount of 20%.

<sup>4</sup> 20<sup>th</sup> resolution: delegation of capital increase with cancellation of shareholders' preferential subscription rights to the benefit of categories of people with specific characteristics. Vester Finance fits well into the target category as a regular investor in so-called "small cap" growth companies, particularly in the health or biotechnology area.

<sup>5</sup> Based on the 18,901,101 shares issuable upon exercise of the dilutive instruments issued by the Company to date.

<sup>6</sup> Based on the 1,748,750 shares that may be issued upon exercise of the dilutive instruments issued by the Company to date.



The number of shares issued under this agreement and admitted to trading will be communicated on the Company's website.

#### **Loans and “PGE Resilience”**

Moreover, on April 26, 2023, the Company obtained the formal agreement on loans for a total amount of €5.3 million with the collective support of “La Région Pays de la Loire”, Bpifrance and its banking pool composed by banks CIC, Crédit Mutuel and BNP to finance its strategic R&D programs. Favorable conditions were granted for these loans, with an interest range of 2-4% and reimbursement timelines within 3 to 5 years. Part of these loans is composed by a “PGE Resilience” (“Prêt Garanti par l’État”) loan guaranteed by the French State, implemented in the context of the Ukrainian crisis.

This available cash will enable the Company to support clinical development and R&D costs. The Company has now a financial visibility until Q2 2024.

#### **2022 Financial results**

Audit procedures have been performed and audit reports are currently being issued.

The Company recorded a consolidated operating loss of €-18 million. Current operating expenses were €36.6 million (versus €42.9 million in 2021) of which 80% related to R&D. R&D expenses amounted to €27 million.

**APPENDICES**

**CONSOLIDATED PROFIT & LOSS**

<b>P&amp;L IN K€</b>	<b>December 31, 2022</b>	<b>December 31, 2021</b>
Turnover	18,302	26,306
Other operating income	0	0
<b>Total Revenues</b>	<b>18,302</b>	<b>26,306</b>
Research and development expenses	(26,893)	(30,550)
Overhead expenses	(6,672)	(8,608)
Expenses related to shares payments	(3,130)	(3,773)
<b>OPERATING PROFIT/LOSS - CURRENT</b>	<b>(18,392)</b>	<b>(16,625)</b>
Other operating products (badwill)		0
Other operating expenses	(84)	0
<b>OPERATING PROFIT/LOSS</b>	<b>(18,476)</b>	<b>(16,625)</b>
Financial products	2,079	267
Financial expenses	(1,624)	(856)
<b>PROFIT/LOSS BEFORE TAX</b>	<b>(18,022)</b>	<b>(17,213)</b>
Income Tax	263	364
<b>NET PROFIT/LOSS</b>	<b>(17,760)</b>	<b>(16,850)</b>
<i>Of which consolidated net result attributable to shareholders</i>	<i>(17,760)</i>	<i>(16,850)</i>
<b>Net earnings attributable to shareholders</b>		
Weighted average number of shares outstanding	<b>18,527,401</b>	<b>18,154,978</b>
<b>Basic earnings per share</b>	<b>(0,96)</b>	<b>(0,93)</b>
<b>Diluted earnings per share</b>	<b>(0,96)</b>	<b>(0,93)</b>

<b>IN K€</b>	<b>2022</b>	<b>2021</b>
<b>NET RESULT</b>	<b>(17,760)</b>	<b>(16,850)</b>
<i>Amounts to be recycled in the income statement:</i>		
Unrealized gains on securities available for sale, net of tax		
Currency conversion difference	(61)	(55)
<i>Amounts not to be recycled in the income statement:</i>	122	25
Other comprehensive income in the period	<b>(61)</b>	<b>(29)</b>
<b>GLOBAL PROFIT/LOSS</b>	<b>(17,699)</b>	<b>(16,879)</b>

**CONSOLIDATED BALANCE SHEET**

<b>ASSETS IN K€</b>	<b>December 31, 2022</b>	<b>December 31, 2021</b>
Acquired R&D costs	48,784	51,122
Tangible assets	743	926
Right-of-use assets	4,236	4,513
Financial assets	635	936
Differed tax assets	182	173
<b>TOTAL NON CURRENT ASSETS</b>	<b>54,581</b>	<b>57,670</b>
Trade receivables	403	772
Other current assets	11,177	9,854
Tax accounts receivables	0	0
Current financial assets	0	0
Cash and cash equivalents	25,620	33,579
<b>TOTAL CURRENT ASSETS</b>	<b>37,200</b>	<b>44,206</b>
<b>TOTAL ASSETS</b>	<b>91,781</b>	<b>101,876</b>

<b>EQUITY &amp; LIABILITIES IN K€</b>	<b>December 31, 2022</b>	<b>December 31, 2021</b>
<b>SHAREHOLDERS' EQUITY</b>		
Stated capital	3,705	3,705
Share premium	38,784	38,778
Merger premium	26,827	26,827
Treasury stock	(549)	(160)
Reserves and retained earnings	(18,349)	(4,411)
Consolidated result	(17,760)	(16,850)
<b>TOTAL SHAREHOLDERS' EQUITY</b>	<b>32,658</b>	<b>47,890</b>
<b>NON-CURRENT DEBTS</b>		
Non-current financial liabilities	37,231	30,801
Non-current lease liabilities	3,586	3,965
Non-current deferred tax liabilities	1,514	1,748
Non-current provisions	524	710
<b>TOTAL NON-CURRENT DEBTS</b>	<b>42,856</b>	<b>37,224</b>
<b>CURRENT DEBTS</b>		
Current financial liabilities	3,093	1,611
Current lease liabilities	883	756
Trade payables	8,539	9,607
Corporate income tax liabilities	21	14
Social and tax payables	2,916	3,724
Other debts and accruals	816	1,050
<b>TOTAL CURRENT DEBTS</b>	<b>16,268</b>	<b>16,761</b>
<b>TOTAL LIABILITIES</b>	<b>91,781</b>	<b>101,876</b>

**CONSOLIDATED CASH FLOW STATEMENT1**

In K€	December 31, 2022	December 31, 2021
<b>CONSOLIDATED RESULT</b>	<b>(17,760)</b>	<b>(16,850)</b>
+/- Depreciation, amortization and provision expenses	2,744	2,337
+ Amortization on "right-of-use"	742	687
+/- Shares based payments (1)	2,728	2,944
<b>CASH FLOW BEFORE TAX</b>	<b>(11,545)</b>	<b>(10,881)</b>
+ Financial charges	(3,066)	634
- Income tax expenses	(263)	(364)
- Tax paid	(236)	(332)
+/- Working capital variation (2)	(3,142)	1,025
<b>CASH FLOW FROM OPERATING ACTIVITIES (A)</b>	<b>(18,252)</b>	<b>(9,919)</b>
- Tangible assets increase	(274)	(472)
+/- Financial assets variation	0	0
+/- Mutual funds units accounted in current financial assets	0	0
+/- Loans and advances variation	300	(355)
<b>CASH FLOW FROM INVESTING ACTIVITIES (B)</b>	<b>26</b>	<b>(827)</b>
+ Capital increase (including share premium)		265
+/- Own shares transactions	6	
+ Warrant subscription		
+ Loan subscription	12,056	15,281
- Loan repayment	(1,010)	(40)
- Lease debt repayment (3)	(785)	(549)
- Financial charges		
<b>CASH FLOW FROM FINANCING ACTIVITIES (C)</b>	<b>10,267</b>	<b>14,957</b>
+/- Currency translation transactions (D)		
<b>CASH VARIATION E = (A + B + C + D)</b>	<b>(7,959)</b>	<b>4,211</b>
<b>CASH OPENING BALANCE (F)</b>	<b>33,579</b>	<b>29,368</b>
<b>CASH CLOSING BALANCE (G)</b>	<b>25,620</b>	<b>33,579</b>
<b>DIFFERENCE: E (G-F)</b>	<b>0</b>	<b>0</b>

(1) Warrants and free shares awards granted in 2022 and valued for 2,728 K€

(2) Mainly explained by:

- Decrease in trade receivable for 369 K€
- Increase in other current assets for 1,323 K€
- Decrease in trade accounts payable for 1,067 K€
- Decrease in social and tax payable for 808 K€
- Decrease in other debts for 234 K€

(3) Explained by IFRS16 application, which corresponds to reimbursement of lease debt for 785 K€

## ABOUT OSE Immunotherapeutics

OSE Immunotherapeutics is a biotech company dedicated to developing first-in-class assets in immuno-oncology and immuno-inflammation. The Company's current well-balanced first-in-class clinical pipeline includes:

- **Tedopi®** (immunotherapy activating tumor specific T-cells, off-the-shelf, neoepitope-based): this cancer vaccine is the Company's most advanced product; positive results from the Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer patients in secondary resistance after checkpoint inhibitor failure. Other Phase 2 trials, sponsored by clinical oncology groups, of Tedopi® in combination are ongoing in solid tumors.
- **OSE-279** (anti-PD1): ongoing Phase 1/2 in solid tumors or lymphomas (first patient included). OSE-279 is the backbone therapy of the BiCKI® platform.
- **OSE-127/S95011 - lusvertikimab** (humanized monoclonal antibody antagonist of IL-7 receptor) developed in partnership with Servier; ongoing Phase 2 in ulcerative colitis (sponsor OSE Immunotherapeutics) and ongoing Phase 2a in Sjögren's syndrome (sponsor Servier); ongoing pre-clinical research in leukemia (OSE Immunotherapeutics).
- **FR-104/VEL-101** (anti-CD28 monoclonal antibody): developed in partnership with Veloxis Pharmaceuticals, Inc. in transplantation; ongoing Phase 1/2 in renal transplant (sponsor Nantes University Hospital); Phase 1 ongoing in the US (sponsor Veloxis Pharmaceuticals, Inc.).
- **OSE-172/BI 765063** (anti-SIRPα monoclonal antibody on CD47/SIRPα pathway) developed in partnership with Boehringer Ingelheim in advanced solid tumors; positive Phase 1 dose escalation results in monotherapy and in combination, in particular with anti-PD-1 antibody ezabemlimab; international Phase 1b ongoing clinical trial in combination with ezabemlimab alone or with other drugs in patients with recurrent/metastatic head and neck squamous cell carcinoma (HNSCC) and hepatocellular carcinoma (HCC).

OSE Immunotherapeutics expects to generate further significant value from its two proprietary drug discovery platforms, which are central to its ambitious goal to deliver next-generation first-in-class immunotherapeutics:

- **BiCKI® platform** focused on immuno-oncology (IO) is a bispecific fusion protein platform built on the key backbone component of anti-PD1 combined with a new immunotherapy target to increase anti-tumor efficacy. BiCKI-IL-7 is the most advanced BiCKI® candidate targeting anti-PD1xIL-7.
- **Myeloid platform** focused on optimizing the therapeutic potential of myeloid cells in IO and immuno-inflammation (I&I). **OSE-230** (ChemR23 agonist mAb) is the most advanced candidate generated by the platform, with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

Additional information about OSE Immunotherapeutics assets is available on the Company's website: [www.ose-immuno.com](http://www.ose-immuno.com)

Click and follow us on Twitter and LinkedIn



### Contacts

#### OSE Immunotherapeutics

Sylvie Détry  
[sylvie.detry@ose-immuno.com](mailto:sylvie.detry@ose-immuno.com)  
+33 1 53 198 757

#### French Media: FP2COM

Florence Portejoie  
[fportejoie@fp2com.fr](mailto:fportejoie@fp2com.fr)  
+33 6 07 768 283

#### Investor Relations

Thomas Guillot  
[thomas.guillot@ose-immuno.com](mailto:thomas.guillot@ose-immuno.com)  
+33 6 07 380 431

### Forward-looking statements

This press release contains express or implied information and statements that might be deemed forward-looking information and statements in respect of OSE Immunotherapeutics. They do not constitute historical facts. These information and statements include financial projections that are based upon certain assumptions and assessments made by OSE Immunotherapeutics' management in light of its experience and its perception of historical trends, current economic and industry conditions, expected future developments and other factors they believe to be appropriate.

These forward-looking statements include statements typically using conditional and containing verbs such as "expect", "anticipate", "believe", "target", "plan", or "estimate", their declensions and conjugations and words of similar import. Although the OSE Immunotherapeutics management believes that the forward-looking statements and information are reasonable, the OSE Immunotherapeutics' shareholders and other investors are cautioned that the completion of such expectations is by nature subject to various risks, known or not, and uncertainties which are difficult to predict and generally beyond the control of OSE Immunotherapeutics. These risks could cause actual results and developments to differ materially from those expressed in or implied or projected by the forward-looking statements. These risks include those discussed or identified in the public filings made by OSE Immunotherapeutics with the AMF. Such forward-looking statements are not guarantees of future performance. This press release includes only summary information and should be read with the OSE Immunotherapeutics Universal Registration Document filed with the AMF on 15 April 2022, including the annual financial report for the fiscal year 2021, available on the OSE Immunotherapeutics' website. Other than as required by applicable law, OSE Immunotherapeutics issues this press release at the date hereof and does not undertake any obligation to update or revise the forward-looking information or statements.